REMARKS

The specification has been amended by adding the abstract which appeared on the cover page of the published PCT pamphlet as a new page at the end of the specification.

The Examiner's presumption that the subject matter of the claims was commonly owned at all relevant times is correct.

Claims 1-11, 13 and 14 were rejected under 35 U.S.C. §103(a) as unpatentable over US published application no. 2002/0018588 (Kusch) in view of US Pat. 6,996,430 (Gilboa et al.). This ground of rejection is respectfully traversed. Claim 1 describes a medical system comprising a medical instrument to be guided in a patient body, X-Ray acquisition means for acquiring a two-dimensional X-ray image of said medical instrument, ultrasound acquisition means for acquiring a three-dimensional ultrasound data set of said medical instrument using an ultrasound probe, means for providing a localization of said ultrasound probe within a referential of said X-ray acquisition means, means for selecting a region of interest around said medical instrument in the three-dimensional ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition means, means for converting said first localization of said region of interest within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe, means for generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization. As Claim 11 indicates, an implementation of the present invention enables live guidance of a procedure with an invasive medical instrument such as an electrophysiology probe by means of both live x-ray imaging and live 3D ultrasound imaging. As one skilled in the art would readily appreciate, complex and intensive computation should be avoided if images are to be acquired, aligned and reproduced rapidly enough for real time invasive instrument guidance. An implementation of the present invention does this by only using 2D x-ray imaging rather than 3D, using the coordinate system of one of the imaging modalities rather than a separate coordinate system of a navigation system, and selecting only the region around the invasive instrument for coordinate transformation, rather than trying to align two complete image data sets for image fusion. The combination of these measures, described in Claim 1, make it possible to perform live guidance of an EP procedure.

Kusch is producing fused 3D x-ray and 3D ultrasound images using a C-arm x-ray system, an ultrasound system, and an optical navigation system. To bring the 3D image data sets of the two modalities to a common coordinate system, the x-ray system, the ultrasound scanner 24, and the patient P are tagged with reference elements 6, 7, and 8 of the navigation system. This enables the conversion of all of the image data sets from the imaging systems to a reference coordinate system K. See paragraphs [0027] and [0030]. With both image data sets converted to a common coordinate system, the two 3D image data sets can be fused, or superimposed on one another. See the first sentence of paragraph [0029]. The complexity of aligning two full 3D data sets is seen from Kusch's extensive description of the correction, or "calibration" that must be performed to fully align the data. See paragraphs [0030]-[0033]. Thus, Kusch does not use the coordinate system of the x-ray system as the referential coordinate system as recited in Claim 1. Furthermore, Kusch does not give any thought to imaging invasive instruments. There is no selection of a region of interest around a medical instrument in the 3D ultrasound image as called for by Claim 1. And there is no conversion of the region of interest coordinates of a medical instrument in the ultrasound image to the coordinates of the x-ray system using the localization of the ultrasound coordinates to those of the x-ray system as called for by Claim 1. Thus, Kusch fails to show or suggest at least three of the elements of Claim 1.

Gilboa et al. also use a navigation system (locating system 130) to locate an x-ray system, an ultrasound probe, the patient, and a treatment probe 170. To use the locating system Gilboa et al. attach sensors to each of these objects. They then goes through calibration to align the data sets as described in column 9. The treatment probe is not shown as an image of the probe itself, but a graphic symbol is used to show the location of the probe on a display. Furthermore, Gilboa et al. do not form a true 3D image but a projection image onto a plane. It is seen from the Gilboa et al. patent that Gilboa et al. do not use the coordinate system of the x-ray system, but the coordinate system of their locating system and sensors. They also do not select a region of interest around their probe for coordinate conversion to the coordinates of the x-ray system using the conversion of ultrasound coordinates to x-ray coordinates. Thus, Gilboa et al. lacks the same three elements that are missing from Kusch. It is respectfully submitted that for these reasons the combination of Kusch and Gilboa et al. cannot render Claim 1 and its dependent Claims 2-13 unpatentable.

Claim 14 describes a method of guiding a medical instrument in a patient body, comprising the steps of acquiring a two-dimensional X-ray image of said medical instrument

using an X-ray acquisition system, acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system, localizing said ultrasound probe in a referential of said X-ray acquisition system, selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system, converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system, generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization. An implementation of Claim 14 enables efficient imaging of an invasive procedure by both x-ray and 3D ultrasound imaging by localizing the ultrasound probe to a coordinate reference system of the x-ray acquisition system, selecting a region of interest of the medical instrument within the 3D ultrasound data set that defines a first localization of the region of interest, and converting the first localization of the ultrasound data to a second localization of the x-ray acquisition system, and using the second localization to form a bimodal image of a 2D x-ray image and the 3D ultrasound data of the region of interest. As previously mentioned, both Kusch and Gilboa et al. use a coordinate system of an independent navigation system, an optical navigation system 3 for Kusch and a locating system 130 with multiple sensors in Gilboa et al., both of which require extensive calibration before use. Neither patent shows or suggests localizing an ultrasound probe to the coordinate reference system of an x-ray acquisition system. Furthermore, neither patent suggests selecting a region of interest of a medical instrument within a 3D ultrasound data set. Neither patent suggests converting a localization of a medical instrument within ultrasound data to a localization in the reference coordinate system of an x-ray acquisition system. For these reasons it is respectfully submitted that Claim 14 is patentable over Kusch and Gilboa et al.

Claim 12 was rejected under 35 U.S.C. §103(a) as unpatentable over Kusch and Gilboa et al. as applied to Claim 1 and further in view of US Pat. 5,368,032 (Cline et al.) Cline et al. describes a hyperthermia system where tissue is locally heated by focused ultrasound to destroy target tissue. A PIXSYS optical tracking unit is used to track the orientation of the ultrasound transducer and a symbol representing the position of the ultrasound transducer is superimposed over the MR image used to image the procedure. No invasive medical instrument is used by Cline et al. and the ultrasound transducer is a therapy transducer, not an imaging transducer. Thus, the three elements of Claim 1 which were

absent from Kusch and Gilboa et al. are also not present in Cline et al., which was cited by the Examiner only for the purpose of showing triggering. Since the three patents fail to show many of the elements of Claim 1 and Claim 12 depends from Claim 1, it is respectfully submitted that Claim 12 is patentable over the three patents by reason of its dependency.

The Strommer et al. patent US 7,505,809 which was made of record but not relied upon has been reviewed and is not believed to affect the patentability of the present claims.

In view of the foregoing amendment and remarks, it is respectfully submitted that the abstract is now properly on a separate page of the specification and that Claims 1-14 are patentable over the combination of the Kusch, Gilboa et al., and Cline et al. patents. Accordingly it is respectfully requested that the rejection of Claims 1-14 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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